

Cancer Center Administrators' Forum



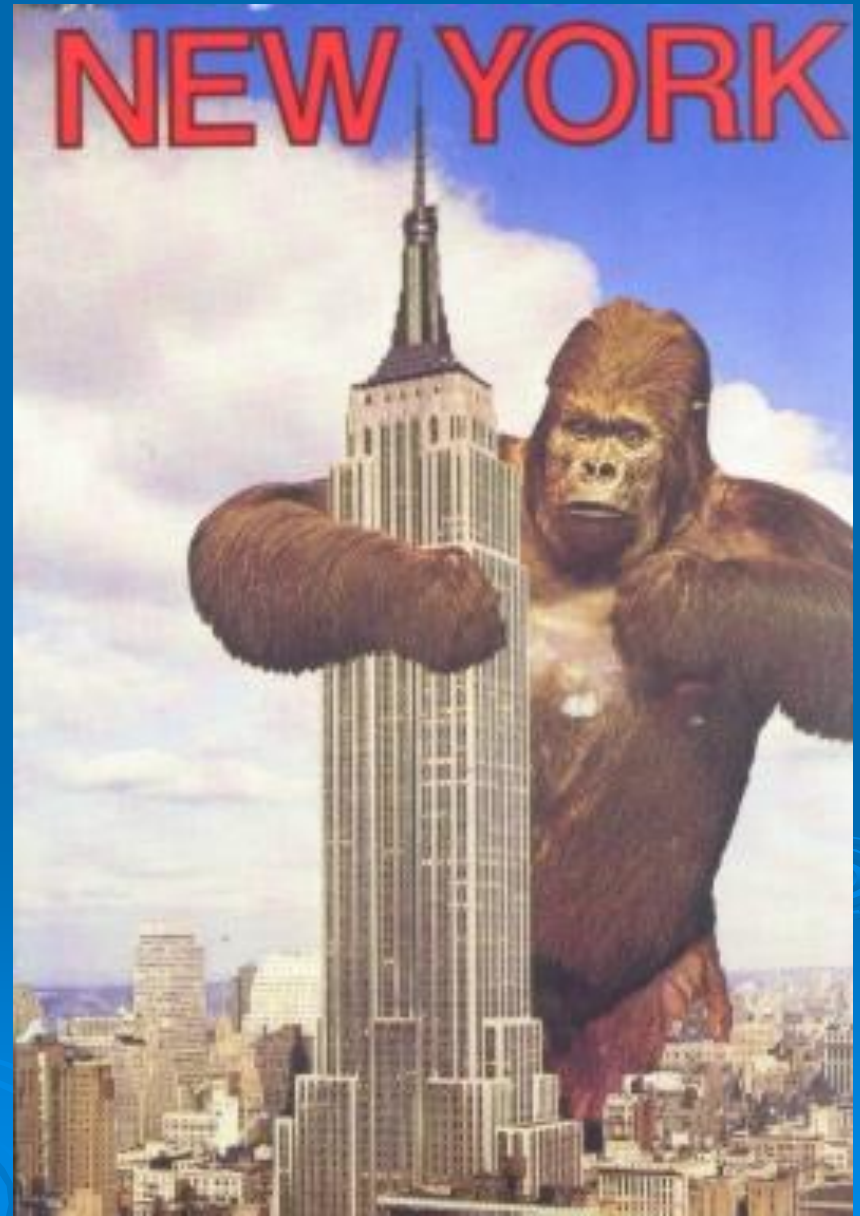
March 16, 2010

Leo F. Buscher Jr.

Director, NCI Office of Grants Administration

Agenda

- NCI Cancer Centers Program
- Budget News
- American Reinvestment & Recovery Act
- Policy Updates
 - Early Submission of Progress Reports
 - Recent Form Changes
 - New Scoring System
 - Federal Financial Report
 - Fiscal Policies
- Legislative Mandates
- Human Stem Cell Research
- Policy Reminders
 - Mandatory Registration of Clinical Trials
 - Protecting Sensitive Data
 - Public Access Policy
- Financial Conflict of Interest
- OLAW and OHRP Updates
- Electronic Submission
- X-Train
- Closeout
- Technical Assistance Resources
- Frequently Asked Questions
- Helpful NIH Resources



Cancer Centers Program

- The NCI Cancer Centers Program was formally established by Congress as a result of the National Cancer Act of 1971.
- Currently there are 65 NCI Designated Cancer Centers
 - 25 Cancer Centers
 - 40 Comprehensive Centers
- Budget in FY 2009: \$286 million
(core grants only)



Budget News

NIH Budget

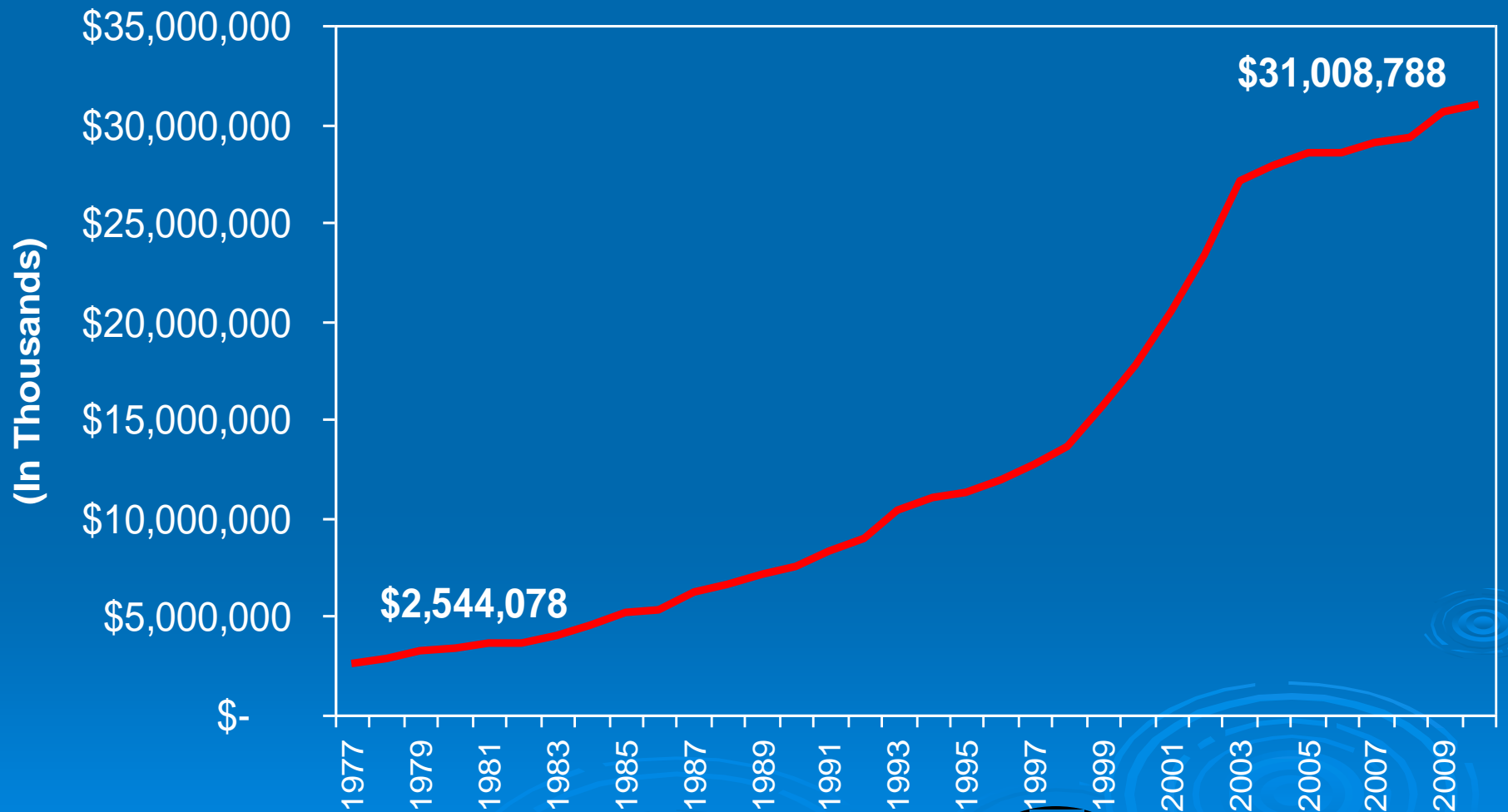


“(T)hese funds will enable the biomedical community to focus considerable energies on discovering new cures, advancing technology, and solving some of our greatest health challenges.”

-Dr. Francis Collins

Director of the National Institutes of Health

NIH Appropriations



NIH FY 2010 Enacted Budget

➤ \$31 billion Budget Authority

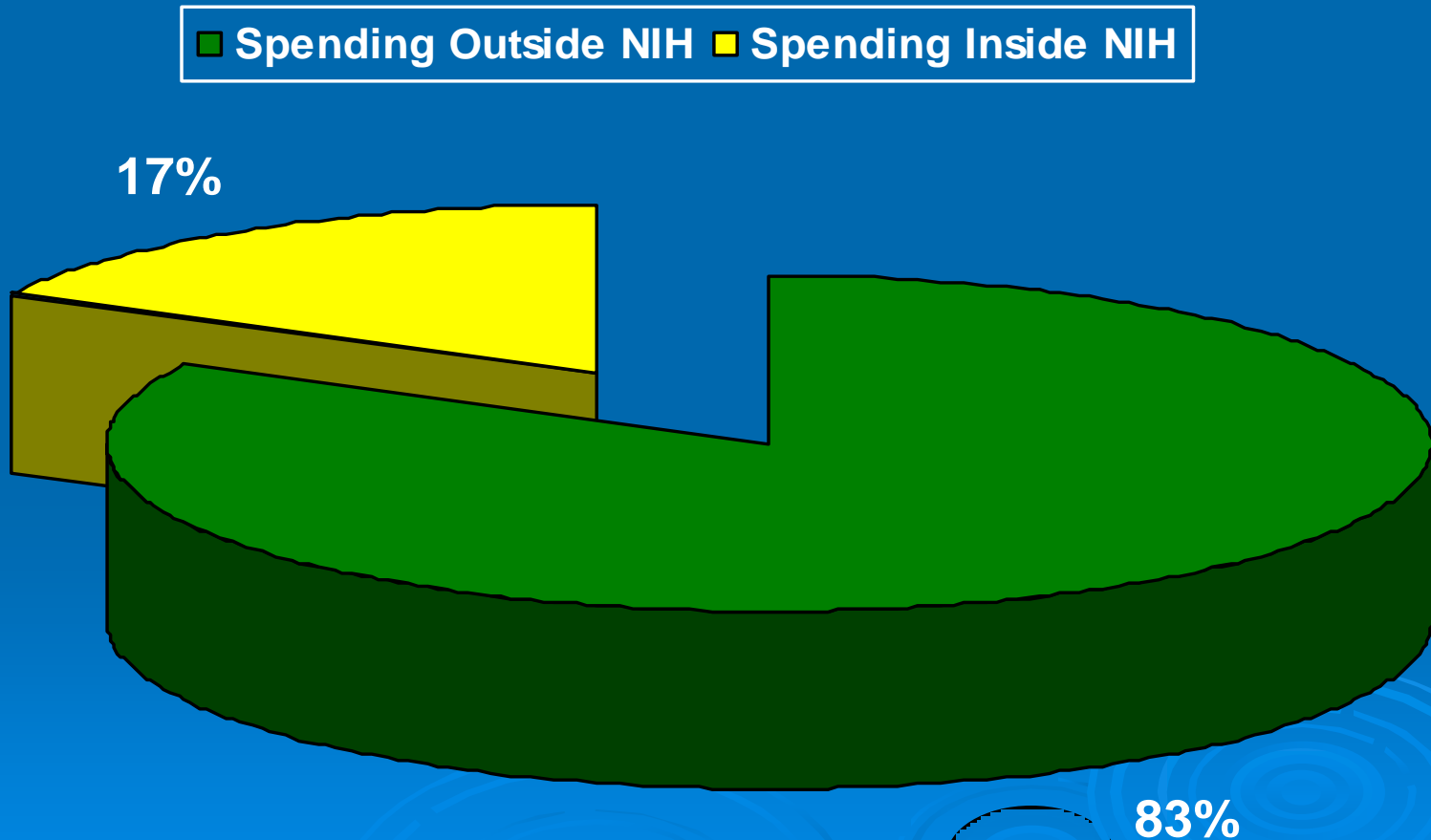
- \$16.6 billion Research Project Grants
 - Over 36,000 grants
- \$3.5 billion R&D contracts
- \$3 billion Research Centers
- \$783 million Training Awards
 - Over 17,000 FTTTPs



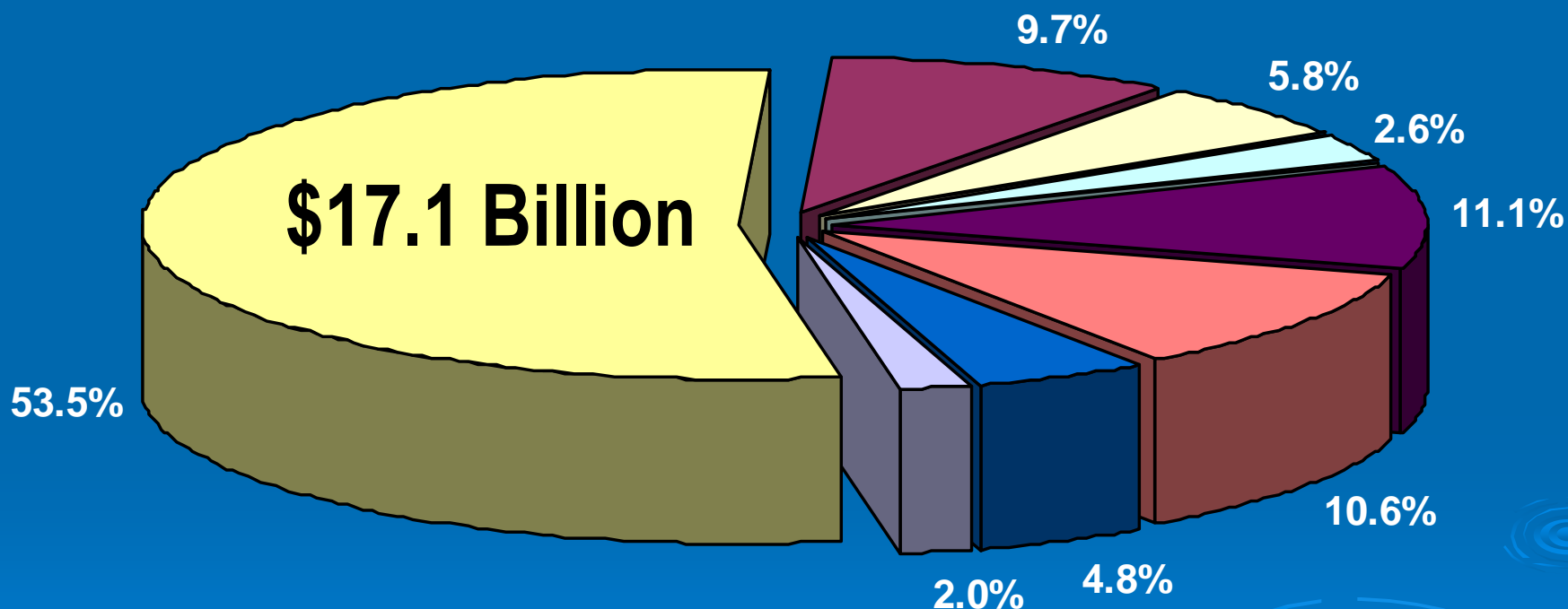
NIH FY 2010 Fiscal Policy for Grant Awards

- **Non-Competing Research Awards:** each IC will use its own discretion to implement compliance with the 2% inflation allowance provided in FY10.
- **Competing Research Awards:** each IC will manage its own portfolio, with average increase of 2% over FY09.
- More at: <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-10-039.html>

2010 NIH Enacted Budget



FY 2011 \$32 Billion Presidential Budget



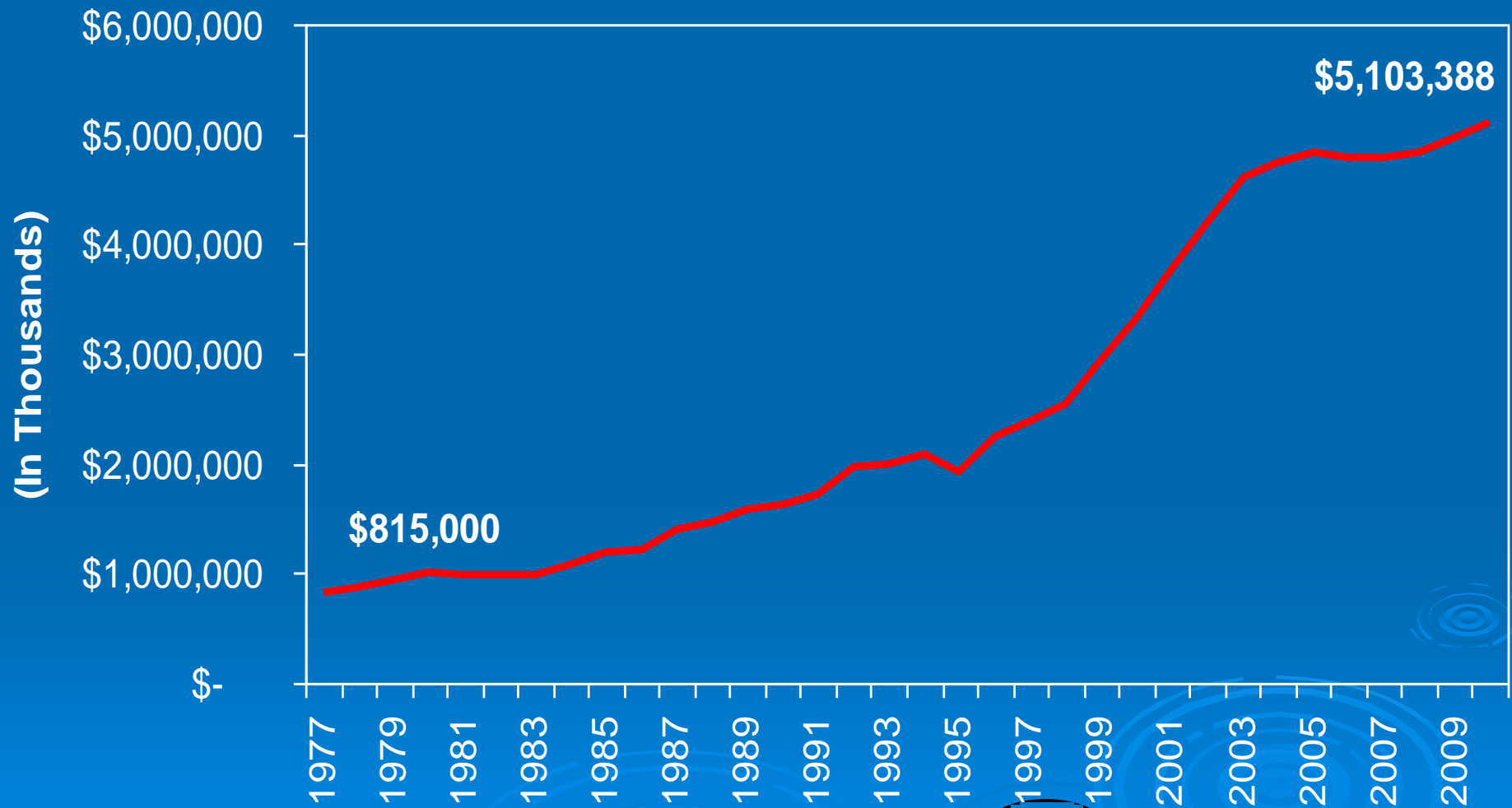
NCI Budget



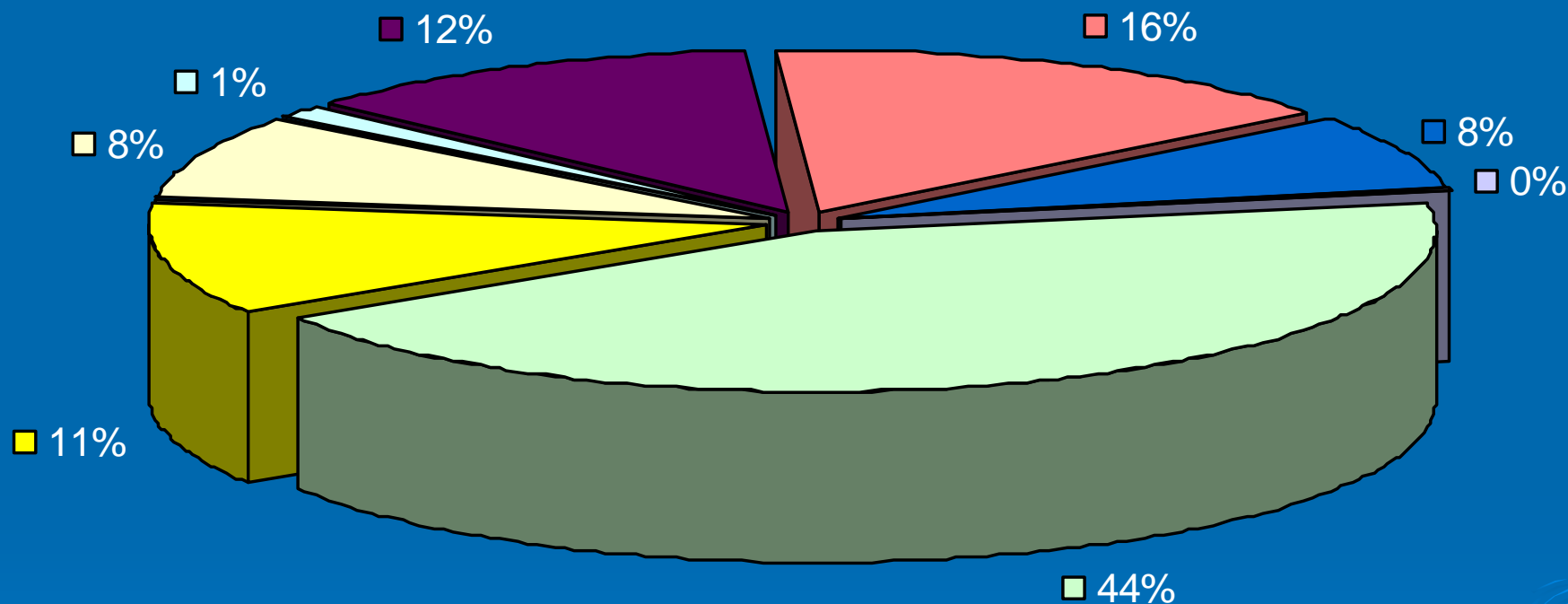
"The National Cancer Institute has more than just a vision... We have developed a coordinated action plan to move cancer research forward in innovative ways."

-Dr. John Niederhuber

NCI Appropriation History

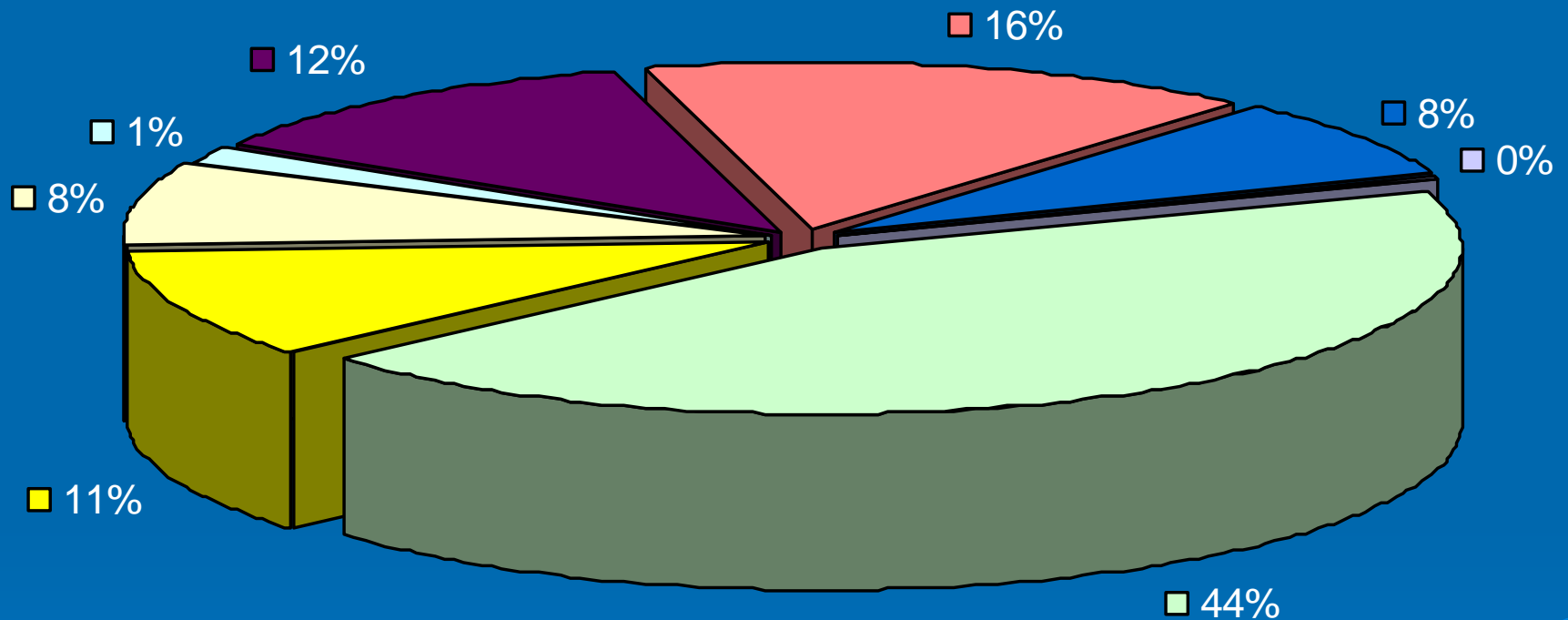


NCI 2010 \$5.1 Billion Enacted Budget



Research Grants	Research Centers	Other Research
Training	R&D	Intramural
Research Mgmt & Support	Other	

NCI 2011 Proposed \$5.2 Billion Budget



■ Research Grants	■ Research Centers	■ Other Research
■ Training	■ R&D	■ Intramural
■ Research Mgmt & Support	■ Other	

NCI FY2010 Paylines and Funding

➤ R01

- Less than 8 modules: 15th percentile
 - Type 1: Funded at 87% of recommended
 - Type 2: Funded at 5% above current award
- 8 modules or more: 15th percentile
 - Type 1: Funded at 83% of recommended
 - Type 2: Funded at 3% above current award
- Large & non-modular: 15th percentile
 - Type 1: Funded at 83% of recommended
 - Type 2: Funded at 3% above current award

NCI FY2010 Paylines and Funding

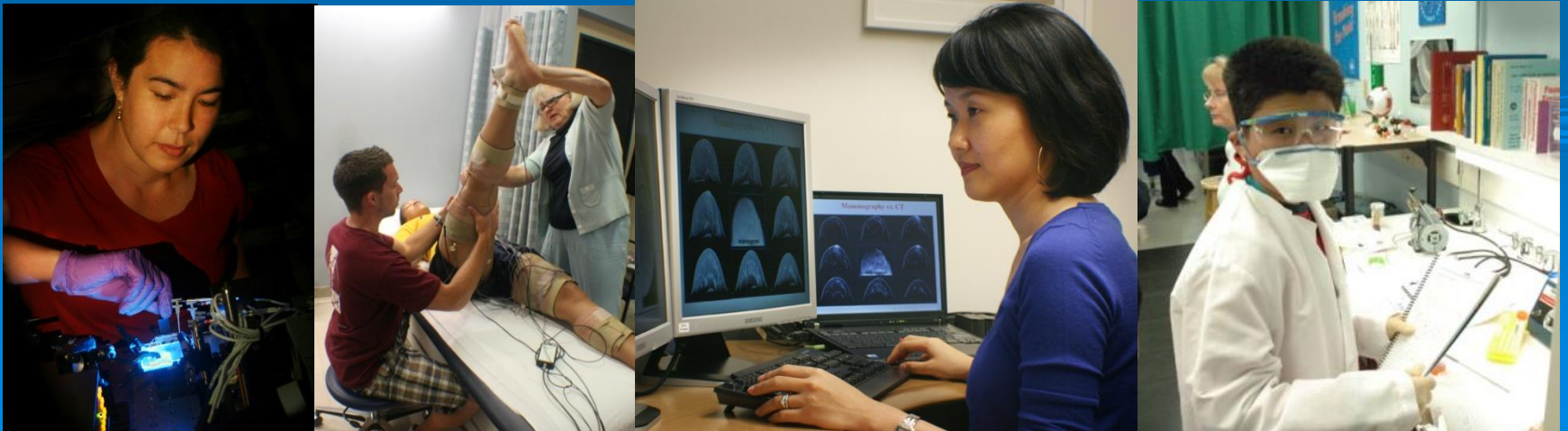
- *R01 (new investigator): 20th percentile
 - Funding policy identical to R01
- R03: 30 priority score
 - Funded at 100% of recommended
- R21 (w/ R33): 12th percentile
 - Funding policy identical to R01
- R21 (w/o R33): 15th percentile
 - Funding policy identical to R01
- P01: Awarded on case-by-case basis
 - Type 1: Funded at 83% of recommended
 - Type 2: Funded at 3% above current award



NIH Implementation of ARRA

American Recovery & Reinvestment Act

- \$10 billion appropriated to NIH
 - Stimulate the economy
 - Create and preserve jobs
 - Advance biomedical research
 - <http://recovery.nih.gov/>



NIH ARRA Funding for Scientific Research

(Dollars In Thousands)

Research Grants	\$ 5,663,653
Research Centers	\$ 540,848
Other Research	\$ 237,783
Training	\$ 47,016
R&D	\$ 790,679
Intramural	\$ 31,799
Research Mgmt & Support	\$ 88,222
Other	<u>\$ 800,000</u>
Total for Scientific Research	\$ 8,200,000

New ARRA NIH-wide Programs

- **\$5.7 billion:** Expand pay line for highly meritorious applications
- **\$1 billion:** Administrative Supplements and Competitive Revisions to existing grants
- **\$200 million:** Challenge Grants
- **\$200 million:** Grand Opportunities (“GO” Grants)
- **\$100 million:** Recruit new faculty to conduct research
- **\$20 million:** Provide summer jobs for high school / college students and teachers to work in science labs

American Recovery & Reinvestment Act at NCI



"The American Reinvestment and Recovery Act is a chance to enhance and to change cancer science. The world is watching, waiting to see what we make of it."

-Dr. John Niederhuber

Research Objectives for Recovery Act Funds

- Accelerate and Expand Cancer Research
- Advance Personalized Cancer Treatment and Prevention
- Redesign Informatics Infrastructure
- Revamp the Clinical Trial System
- Collaborate for Greater Impact
- Strengthen the Research Workforce
- Improve Care and Quality of Life for all Cancer Patients

<http://www.cancer.gov/recovery>

Major NCI ARRA Investments

- \$1.26 billion appropriated to NCI
 - \$175 million: The Cancer Genome Atlas (TCGA)
 - \$80 million: NCI Community Cancer Centers Program (NCCCP)
 - \$60 million: Cancer Human Biobank (caHUB)
 - \$63 million: Cancer Centers Program (P30)
 - \$36 million: Accelerating Clinical Trials of Novel Oncological pathWays (ACTNOW)

ARRA Funding for Cancer Research by Organ Site

Breast Cancer	\$ 85,599,444
Prostate Cancer	\$ 48,762,696
Lung Cancer	\$ 48,001,019
Colorectal Cancer	\$ 44,466,849
Brain Cancer	\$ 38,841,317
Leukemia	\$ 33,865,393

NCI ARRA Grant Funding

•NCI ARRA grants awarded as of 2/19/2010:

	Estimated # of Awards	Estimated Total \$ Awarded
Competing Applications	547	\$223,000,000
Supplements	999	\$325,800,000
Total	1,546	\$591,200,000

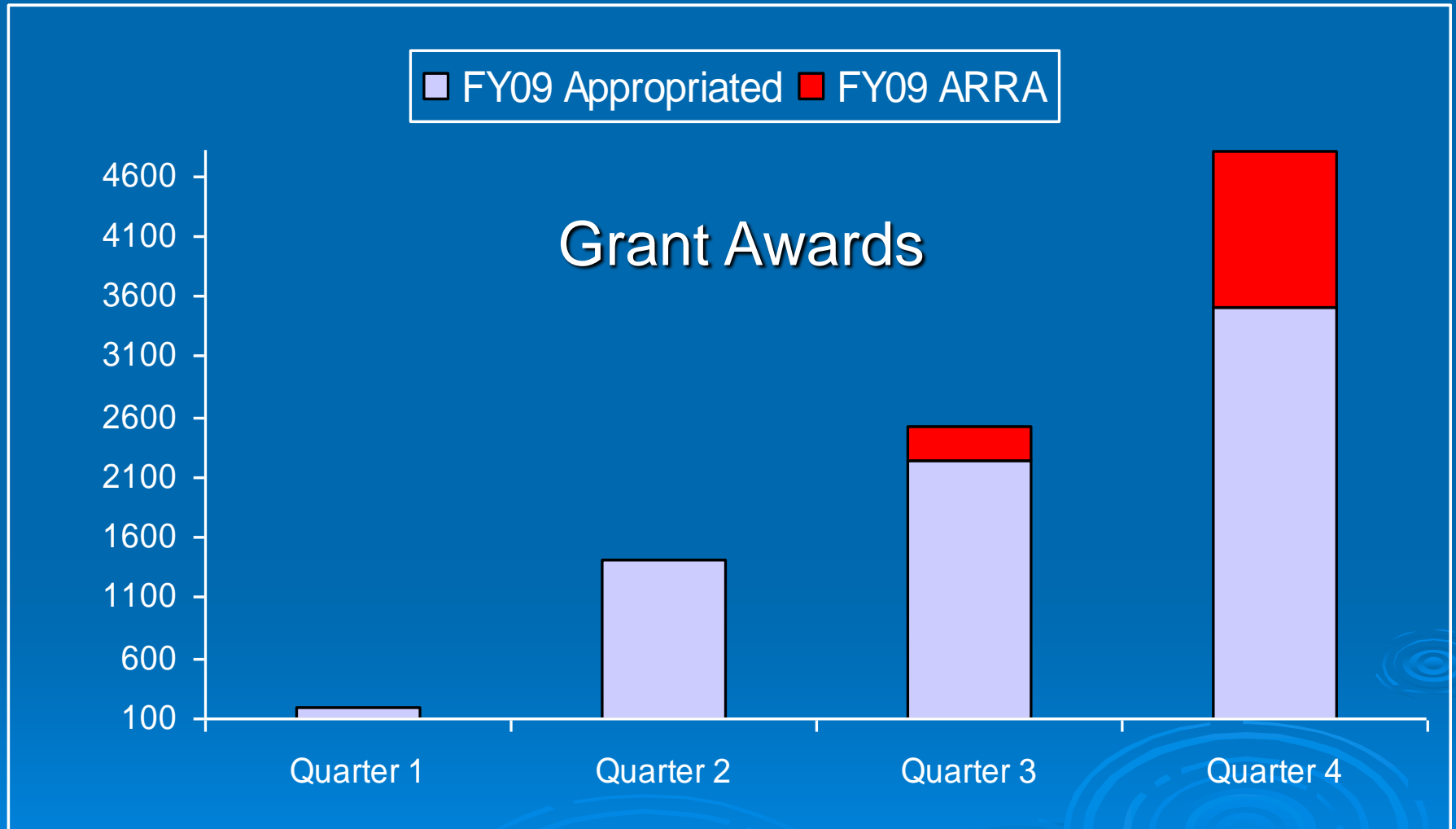
NCI Grant Awards by Quarter in FY09

FY09 Appropriated	Quarter 1	Quarter 2	Quarter 3	Quarter 4	Total
No. of Grant Awards	204	1,410	2,239	3,500	7,353
% of Grant Awards	2.8%	19.2%	30.5%	47.6%	100.0%
Total \$ Awarded	\$93,618,502	\$625,748,727	\$956,350,249	\$1,436,957,089	\$3,112,674,567
% of Total \$ Awarded	3.0%	20.1%	30.7%	46.2%	100.0%

FY09 ARRA	Quarter 1	Quarter 2	Quarter 3	Quarter 4	Total
No. of Grant Awards	-	-	271	1,293	1,564
% of Grant Awards	0.0%	0.0%	17.3%	82.7%	100.0%
Total \$ Awarded	-	-	\$61,935,563	\$460,034,564	\$521,970,127
% of Total \$ Awarded	0.0%	0.0%	11.9%	88.1%	100.0%

FY09 Combined Approp. + ARRA	Quarter 1	Quarter 2	Quarter 3	Quarter 4	Total
No. of Grant Awards	204	1,410	2,510	4,793	8,917
% of Grant Awards	2.3%	15.8%	28.1%	53.8%	100.0%
Total \$ Awarded	\$93,618,502	\$625,748,727	\$1,018,285,812	\$1,896,991,653	\$3,634,644,694
% of Total \$ Awarded	2.6%	17.2%	28.0%	52.2%	100.0%

NCI Grant Awards by Quarter FY09



ARRA Reporting Updates

➤ Changes to reporting include:

- Recipients should report the number of jobs created or retained for the current reporting period only
 - Jobs must be funded by Recovery Act
- Recipients can report jobs that will be reimbursed by ARRA funds at some point in time
- Recipients will be able to correct mistakes on FederalReporting.gov continually throughout each period
- http://www.whitehouse.gov/omb/assets/memoranda_2010/m10-08.pdf

ARRA Reporting Requirements

- All ARRA grants must have unique separate Payment Management System (PMS) accounts and draw downs are from each account.
 - Includes supplements
- Separate Financial Reporting
 - Separate SF 272 and Financial Status Reports will be required to be submitted covering this additional funding.
 - These will be in addition to any required financial reports for the parent grant.

ARRA Reporting Requirements

- Separate closeout documents
 - Separate Final Progress Reports, Final Financial Status Reports (FSRs), and Final Invention Statements will be required to closeout the Recovery Act funding.
 - These closeout reports for the ARRA funding are required even when the parent grant continues.
- ARRA funds are not available for rebudgeting or carryover into the parent grant.
 - Any ARRA funding remaining at the end of the funding period for this award must be reported as an unobligated balance.

Policy Updates



Times Square

Early Submission of Progress Reports for Select NCI Grants

- NCI Applications that have large grants cycling in the fourth quarter are being asked to submit progress reports one month early.
- This initiative is focusing on large grants (P30s, P50s, U54s) that are scheduled for funding in July, August, and September.
- NCI is requesting 120 early progress reports from 69 different grantees.
- As a result, NCI will be able to obligate funds earlier in the fiscal year, and delays will be avoided in issuing grant awards.
- NOTE: This program only applies to NCI Grant Awards - it is not NIH-wide

Recent Form Changes



Restructured Applications and Instructions: SF 424 (R&R) and PHS 398

- Implementation of goal: Align the structure and content of applications with review criteria, and shorten the length of applications.
- Three sections of application instructions revised:
 - Research Plan
 - Biographical Sketch
 - Resources and Facilities
- Shorter Page Limits
- For additional information see:
<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-09-149.html>
and <http://enhancing-peer-review.nih.gov>

Research Plan Changes

- New **Research Strategy** section replaces 3 sections of the current Research Plan.
- Sections that are being replaced include:
 - Background and Significance
 - Preliminary Studies/Progress Report
 - Research Design and Methods
- New **Research Strategy** subsections include:
 - Significance
 - Innovation
 - Approach
 - Progress report for renewal/revision applications
 - Preliminary studies for new applications (can be placed anywhere in the Research Strategy Section)
- More at: <http://enhancing-peer-review.nih.gov>

Biographical Sketch Changes

- **Personal Statement:** Tell us why your experience and qualifications make you particularly well-suited for your role in the project.
 - Does not apply to participating faculty on Ts
- **Publications:**
 - Include no more than 15
 - Make selections based on recency, importance to the field, and/or relevance to the application.
- Page limit remains at 4
- More at: <http://enhancing-peer-review.nih.gov>

Resources and Facilities Changes

- Provide a description of how the scientific environment will contribute to the probability of success of the project.
- For Early Stage Investigators, describe the institutional investment in the success of the investigator.
- In Select Agent Section of the Research Plan, describe the biocontainment resources available at all performance sites.
- More at: <http://enhancing-peer-review.nih.gov>

Shorter Page Limits

Introduction Except Intro to Resubmission for Ts, K12, and R25	1 page
Specific Aims	1 page
Research Strategy R03, R13/U13, R21, R36, R41, R43, Fs, SC2, SC3	6 pages
Research Strategy R01, single project U01, R10, R15, R18, U18, R21/R33, R24, R33, R34, U34, R42, R44, DP3, G08, G11, G13, UH2, UH3, SC1	12 pages
Candidate Information + Research Strategy Career Development Awards (Ks, except K12)	12 pages
Research Training Program Plan Including NRSA (Ts), K12 and R25	25 pages

Restructured Application Forms/Instructions **Must** Be Used For Due Dates After **January 25, 2010**

- To implement changes for the Peer Review initiative and changes to the SF 424 R&R, new application packages were posted in December, along with new Parent Announcements and updated active FOAs.
- Resubmissions must use new application forms and instructions (and shorter page limits).
- More at: <http://enhancing-peer-review.nih.gov>

Revised Progress Report: PHS 2590

- Use required as of 10/01/2009 (eSNAP updated 10/2009)
- Key Personnel Report has changed to an All Personnel Report
 - The PI and co-PIs must be reported as well as all personnel that contribute more than 1 person month (PM) to the project
 - The PD/PI(s) and all postdocs must include their Commons ID
- More at: <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-09-139.html> and <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-09-150.html>

Revised Progress Report: PHS 2590

- The progress summary page now requires the grantee to report changes to the innovative potential of the project, if applicable.
- For new key personnel being added to the project, the biosketch must include a personal statement to address their experience and qualifications that make them particularly well-suited for the project.

New Scoring System for NIH Grant Applications

- The new scoring system was implemented for the summer 2009 review cycle, as a part of the Enhancing Peer Review initiative at the NIH.
- The prior scoring system ranged from 1.0 to 5.0 in 0.1 increments.
 - This system was changed because it is difficult to make 41 reliable discriminations of application merit.
 - In addition, the usefulness of scores for funding decisions was reduced as ratings became increasingly positive and the score range became compressed.

New Scoring System for NIH Grant Applications

- A 9-point rating scale is now used for each of the five review criteria and for the overall impact/priority of each application.
- There are descriptors associated with each rating that encourage the use of the full scoring range.
 - 1 = Exceptional (Exceptionally strong with essentially no weaknesses)
 - 5 = Good (Strong but with at least one moderate weakness)
 - 9 = Poor (Very few strengths and numerous major weaknesses)
 - See http://enhancing-peer-review.nih.gov/scoring&review_changes.html for the complete and detailed description of all potential scores.

Criterion Scoring

- In most cases, up to five individual criteria are scored, but certain funding announcements may include more than five scored criteria.
- The criterion scores appear in a table at the beginning of each critique in the summary statement.

Impact/Priority Score

- This score is based on the reviewer's assessment based on the five criteria scored plus additional criteria.
- Some applications do not receive a numeric score.

Percentile Rank

- In addition, most applications receive a percentile rank. The conversion of priority scores to percentile rankings is based on scores assigned to applications reviewed during the current plus the past two review rounds.
- The overall intent of percentile ranking is to improve the comparability of scored applications. The percentile/priority score is the primary indicator of relative scientific merit when applications are being considered for funding within an institute.

Federal Financial Report

- Federal Financial Report (FFR or SF-425/SF-425A):
 - New requirement from the Office of Management and Budget.
 - Consolidates the Financial Status Report (FSR or SF-269/SF-269A) and the Federal Cash Transaction Report (FCTR or SF-272/SF-272A) into a single form.
- Reporting periods and due dates will be standardized as well.
- More at: <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-10-038.html>

Federal Financial Report

- Effective January 1, 2010: Grantees must report cash transaction data via the Payment Management System (PMS) using the FFR cash transaction data elements.
 - The first quarter fiscal year 2010 report, covering October 1, 2009 through December 31, 2009, must be filed within 30 days of the end of the quarter.
 - This is a change from the 45 days allowed when filling the PSC 272.
 - This replaces the use of the Federal Cash Transaction Report.
 - See <http://www.dpm.psc.gov/> for additional information and training.
- Grantees should continue to use the eFSR system in the eRA Commons to report actual expenditures until notified otherwise.
 - Access to the FFR is granted by using the same username and password which is used to make payment requests in the Payment Management System.

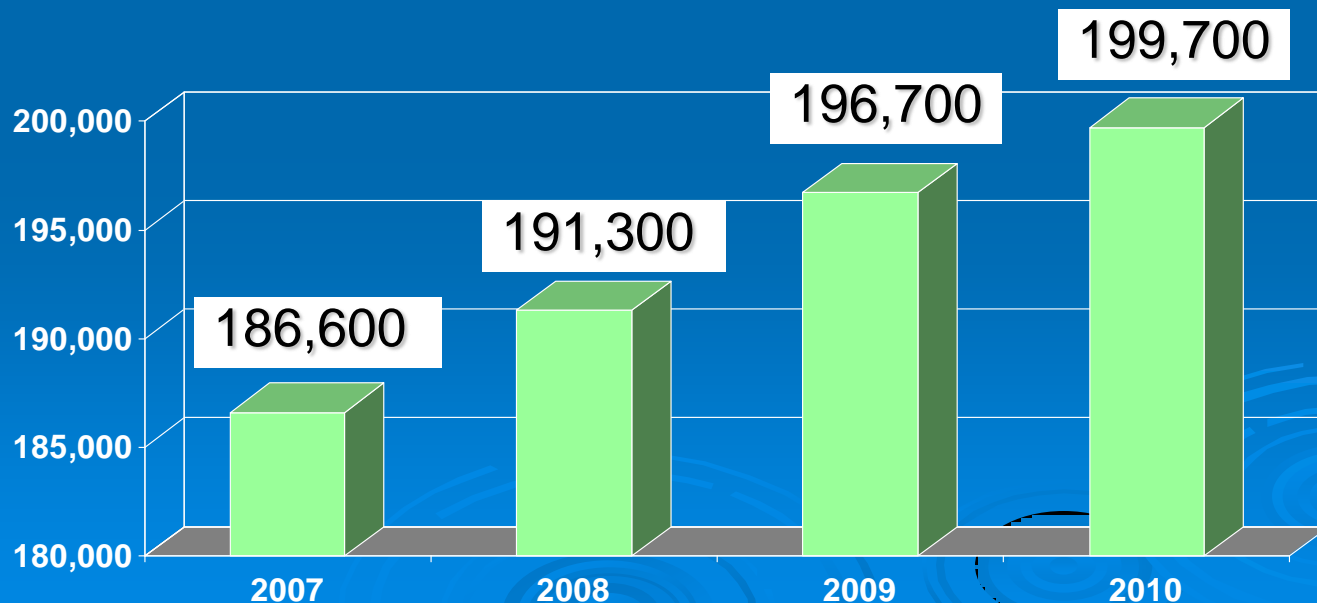


Fiscal Policies

Legislative Salary Cap
Kirschstein-NRSA Stipend Levels

Salary Limitation on Grants, Cooperative Agreements, and Contracts

- Restricts the amount of direct salary under a grant or contract to Executive Level I of the Federal Executive Pay Scale.
- Salary Cap Summary (Historical Information):
http://grants.nih.gov/grants/policy/salcap_summary.htm
- More at: <http://grants.nih.gov/grants/guide/notice-files-NOT-OD-10-041.html>



FY2010 Ruth L. Kirschstein-National Research Service Award Stipend Levels

- Stipend levels have been increased by 1%.
- The new stipend levels apply to all individuals receiving support through institutional research training grants or individual fellowships, including the Minority Access to Research Center (MARC) and Career Opportunities in Research (COR) programs.
- Tuition and Fees, Training Related Expenses on Institutional Training Grants, and the Institutional Allowance for Individual Fellows remain unchanged.
- More at: <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-10-047.html>

Legislative Mandates in Effect for FY2010



New York Supreme Court

Acknowledgment of Federal Funding

- When issuing statements, press releases, RFPs, and other communication describing projects funded in whole or in part with Federal money, all grantees shall clearly state:
 - (1) the percentage of the total costs of the program or project which will be financed with Federal money;
 - (2) the dollar amount of Federal funds for the project or program; and
 - (3) percentage and dollar amount of the total costs of the project or program that will be financed by non-governmental sources.

Restriction of Funding of Certain Human Embryo Research

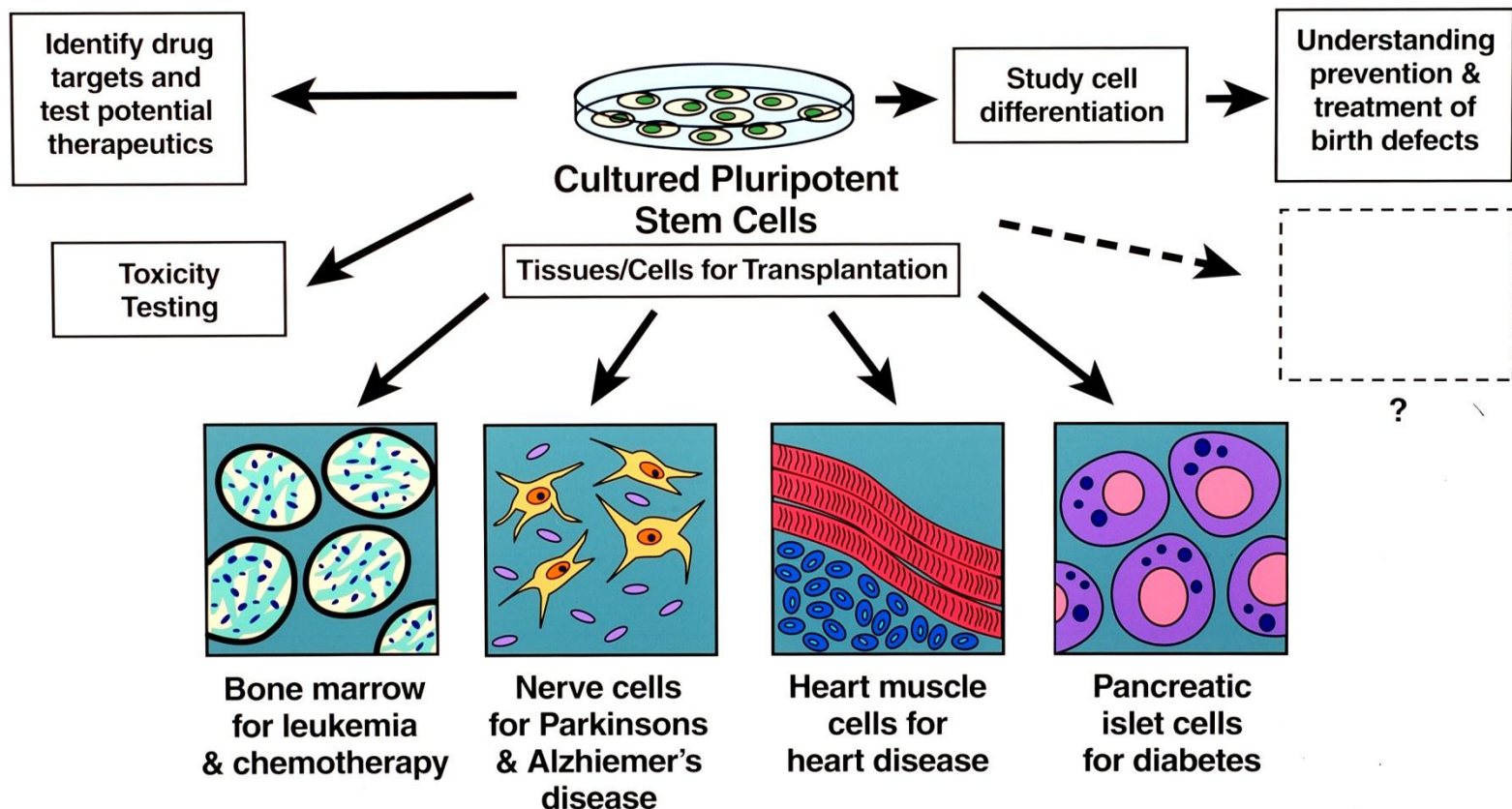
- No awarded funds shall be used for:
 - The creation of human embryos for research purposes
 - Research in which embryos are destroyed, discarded or knowingly subjected to risk of injury or death greater than allowed for under 45 CFR 46.204(b) and 42 USC 289g(b)
- Additional definitions can be found at:
 - <http://grants2.nih.gov/grants/guide/notice-files/NOT-OD-10-040.html>

Human Stem Cell Research



Human Embryonic Stem Cells (hESC)

The Promise of Stem Cell Research



hESC Background

- March 2009 – President Obama issued Executive Order 13505
 - Prior to Executive Order, Research limited to 21 established Stem Cell Lines
- Establishes NIH hESC Registry
- Final Guidelines Effective July 7, 2009
 - <http://stemcells.nih.gov/index.asp>

NIH Guidelines on Human Stem Cell Research – 7/7/09

- Established criteria for NIH review of Human Embryonic Stem Cells (hESCs) to be included in new Registry as eligible for use in NIH funding
- Centralize processes and procedures for NIH reviews of hESCs
- Organizations submitting information about hESCs for potential inclusion in the Registry must use NIH Form 2890 (web-based form)
- More at: <http://stemcells.nih.gov>

NIH hESC Registry

- Grantees may only use lines listed on the new Registry
- Old cell lines are not grandfathered into the new Registry
- First 13 lines approved 12/2/09
- As of 3/1/2010:
 - 43 lines are currently approved
 - 115 lines are currently pending NIH review

hESC Guidelines

- Applications Pending Review and Award:
 - Applicant institution must provide letter signed by Authorized Organizational Representative stating which line(s) from the Registry are available to grantee and will be used under the award.
 - Inclusion of letter in Just-In-Time encouraged
 - Should include description of what impact the use of a new line will have on project
 - Until hESC lines are listed on the Registry, applicants should not specify specific hESC line, but should include statement that one from the Registry will be used.
 - Check box in application “Specific stem cell line cannot be referenced at this time. One from the Registry will be used.”

hESC Guidelines

➤ Inquiries should be directed to:

Division of Grants Policy

Office of Policy for Extramural Research Administration

National Institutes of Health

6705 Rockledge Drive, Suite 350

Bethesda, MD 20892

Email: GrantsPolicy@od.nih.gov

hESC Resources

➤ Stem Cell Registry

- http://grants.nih.gov/stem_cells/registry/current.htm

➤ Guide Notices

- <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-09-123.html>
- <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-10-020.html>

➤ Request for hESC line approval (Form 2890)

- http://hescregapp.od.nih.gov/NIH_Form_2890_Login.htm

➤ FAQs

- <https://stemcells.nih.gov/info/faqs.asp>

An aerial photograph of Central Park in New York City, showing the dense greenery of the park surrounded by the dense urban landscape of Manhattan. The Hudson River and the George Washington Bridge are visible in the background. The text "Policy Reminders" is overlaid in the center of the image.

Policy Reminders

Central Park

Mandatory Registration of Clinical Trials

➤ Mandatory Registration

- All “applicable clinical trials” of drugs, biologics, and devices are to be registered in the ClinicalTrials.gov database by the responsible party.
 - Includes Phase II-IV clinical trials of drugs and devices subject to FDA regulation.
 - Not limited to trials for serious or life threatening diseases.
- NIH will verify registration before funds are released.
 - Competing applications and progress reports with NIH-funded trials must include a certificate of submission.
- Civil penalties will be levied for noncompliance if trials are not properly registered.

➤ Results Reporting

- Public Law 110-85 mandates the establishment of a clinical trials results database. Effective September 27, 2008, the NIH launched an expanded ClinicalTrials.gov database that can accept “basic results” information.

- More at <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-09-077.html> and <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-08-023.html>

Renewed Focus on Protecting Sensitive Data in Research

- Federal Information Security Management Act (FISMA) requires that all information systems which contain Federal data, electronic or hard copy, must be protected from unauthorized access. (Public Law 107-347)
 - Access to data should be limited through password protection and other appropriate means.
 - Personally identifiable, sensitive and confidential information should not be housed on portable electronic devices, but if they must be used the data should be encrypted.
- FISMA applies to grantees, but only when they collect, store, process, transmit, or use information on behalf of HHS.
- **All grantees have a responsibility to protect personally identifiable, sensitive, and confidential data.**

Public Access Policy: Now Permanent

“All investigators funded by NIH must submit to PubMed Central an electronic version of their final, peer-reviewed manuscripts upon acceptance for publication.”

- Compliance is mandated by Public Law 110-161
- Applicable to:
 - Peer-reviewed articles,
 - Accepted for publication on or after 4/7/08, and
 - Arising from direct grant or contract funds active in FY 2008 and beyond.
- Full-text articles must be made publicly available on NLM's PubMed Central no later than 12 months after the date of publication.
- More at: <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-09-071.html>

NIH Public Access Policy Compliance

- Compliance with the NIH Public Access Policy is an institutional responsibility. Failure to provide evidence of compliance in an application, proposal or report is a violation of the terms and conditions of the NIH award.
- NIH may suspend awards found to be out of compliance, pending corrective action, or may terminate the award for cause.
(per 45 CFR 74.61, 74.62, and 92.43)
- More at: <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-09-136.html> and <http://publicaccess.nih.gov>

Public Access Policy

➤ Questions should be directed to:

Office of Extramural Research

National Institutes of Health

1 Center Drive, Room 144

Bethesda, MD 20892-0152

E-mail: PublicAccess@nih.gov

Website: <http://publicaccess.nih.gov>

A nighttime photograph of the New York Stock Exchange building, a grand neoclassical structure with a prominent portico of six columns and a pediment featuring a relief sculpture. The building is illuminated, and three American flags are visible in front of the columns. The text "NEW YORK STOCK EXCHANGE" is inscribed above the columns. The building is flanked by other tall city buildings, and the foreground shows a street with a metal fence and concrete barriers.

Financial Conflict of Interest

IOM Calls for More Regulation to Reduce Conflict of Interest

- On 4/28/09, the Institute of Medicine (IOM) issued a report calling for major voluntary and regulatory actions to reduce conflicts of interest in medical research, education, and practice.
- The report, entitled *Conflict of Interest in Medical Research, Education, and Practice*, recommends:
 - That the “format for disclosure and categories of relationships” be standardized across institutions, and
 - Congress should require pharmaceutical, biotechnology, and device firms to report through a public Website the payments they make to doctors, researchers, academic health centers, professional societies, patient advocacy groups, and others involved in medicine.

Advanced Notice of Proposed Rulemaking (ANPRM)

- “NIH Requests Comments on Proposed Amendment of Regulations on the Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Service Funding is Sought and Responsible Prospective Contractors”
 - Published May 8, 2009 in the NIH Guide to Grants and Contracts
 - More at <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-09-099.html>
- Federal Register (Vol. 74, No. 88) May 8, 2009
 - <http://edocket.access.gpo.gov/2009/pdf/E9-10666.pdf>
- 60-day comment period – closed July 7, 2009
 - 78 comments received and considered
- All comments are posted at:
<http://www.regulations.gov/search/Regs/home.html#docketDetail?R=NIH-2008-0002>

Advanced Notice of Proposed Rulemaking (ANPRM)

- ANPRM addresses various topics, including:
 - Expanding the scope of regulation and disclosure of interests;
 - Definition of “Significant Financial Interest”;
 - Identification and management of conflicting interests by institutions;
 - Assuring institutional compliance;
 - Requiring institutions to provide additional information;
 - Broadening the regulations to address institutional conflict of interest.

Notice of Proposed Rulemaking (NPRM)

- NIH has considered comments submitted in response to the ANPRM and on behalf of the Department of Health and Human Services and the Public Health Service has prepared a NPRM which proposes changes to the regulations.
- The NPRM is under review and clearance.
- NPRM will be published in the Federal Register for public comment.
- A Final Rule is expected to be published this year.

eRA Commons

FCOI Module/Reporting Tool

- Enables grantees to report identified FCOIs to NIH through the eRA Commons.
- System allows institutions to:
 - Initiate and send a new FCOI report electronically through the eRA Commons
 - Search previously created records
 - Edit a previously submitted record
 - Respond to a request for additional information
 - Rescind a previously submitted record
 - View a history of actions
- Effective July 1, 2009 the system will be mandatory for all NIH grants and cooperative agreements.
- To prepare, Institutional Signing Officials must assign FCOI roles to users in the eRA Commons.
- More at <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-09-072.html>

Updated and Expanded FAQs on FCOI

- For all NIH-supported institutions
- Categorized for ease of reference:
 - General Questions
 - Institution-Specific Questions
 - Investigator-Specific Questions
- Web Postings and Resources at:
<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-08-063.html>
and <http://grants.nih.gov/grants/policy/coifaq.htm>

FCOI Web-Based Tutorial

- Reviews requirements of and responsibilities for compliance with Federal FCOI regulations.
- Designed for use by:
 - **Institutional officials** responsible for managing NIH-funded grants, cooperative agreements and/or contracts
 - **Individuals** who are responsible for the design, conduct or reporting of NIH-supported research
- Includes quizzes to test understanding and a Certificate of Completion.
- More at: <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-08-106.html>

OLAW and OHRP Updates



Animal Welfare: OLAW Compliance Assistance

- *“What Investigators Need to Know About the Care and Use of Laboratory Animals”*
 - Brochure explains the requirements for using animals in PHS-supported research.
 - Contact OLAW to request multiple copies.
- FAQs on *“PHS Policy on Humane Care and Use of Vertebrate Animals”* are available on the OLAW website.
- IACUC 101
 - Series of workshops on the roles and responsibilities of IACUCs, including federal policies and regulations regarding animal welfare.
 - A list of IACUC workshops can be found at <http://grants.nih.gov/grants/olaw/iacuc101s.htm>

Consortium Agreements: Subawards and Animals

- The prime grantee is accountable to NIH and must confirm Assurance and IACUC approval (dated within 3 years of the project or budget start date).
- Animal welfare requirements apply to all consortium participants and sub-projects.
 - Inter-Institutional Assurance is needed:
 - Prime grantee has no animal program; animal work is being conducted at an Assured performance site.
 - Foreign Assurance is needed:
 - Direct support to a foreign institution.
 - Domestic prime grantee with a foreign performance site using animals.
 - Domestic grantee's IACUC approves animal activities performed at the foreign site.
- Grants Policy Statement Page 224 at:
http://grants.nih.gov/grants/policy/nihgps_2003/index.htm

Human Subjects: Registration Requirements for Institutional Review Boards

- Published in the Federal Register on January 15, 2009 and effective July 14, 2009.
- OHRP has added a new subpart E to the HHS protection of human subjects regulations, which requires IRBs to register with HHS.
- Registration information includes contact information, approximate numbers of all active protocols and active protocols involving research conducted or supported by HHS, and staffing for the IRB.
- Initial registration was due by September 14, 2009.
- Registration does not mean OHRP has determined that the IRB is in compliance with Protection of Human Subjects regulations at 45 CFR Part 46.

More at: <http://edocket.access.gpo.gov/2009/E9-588.htm>

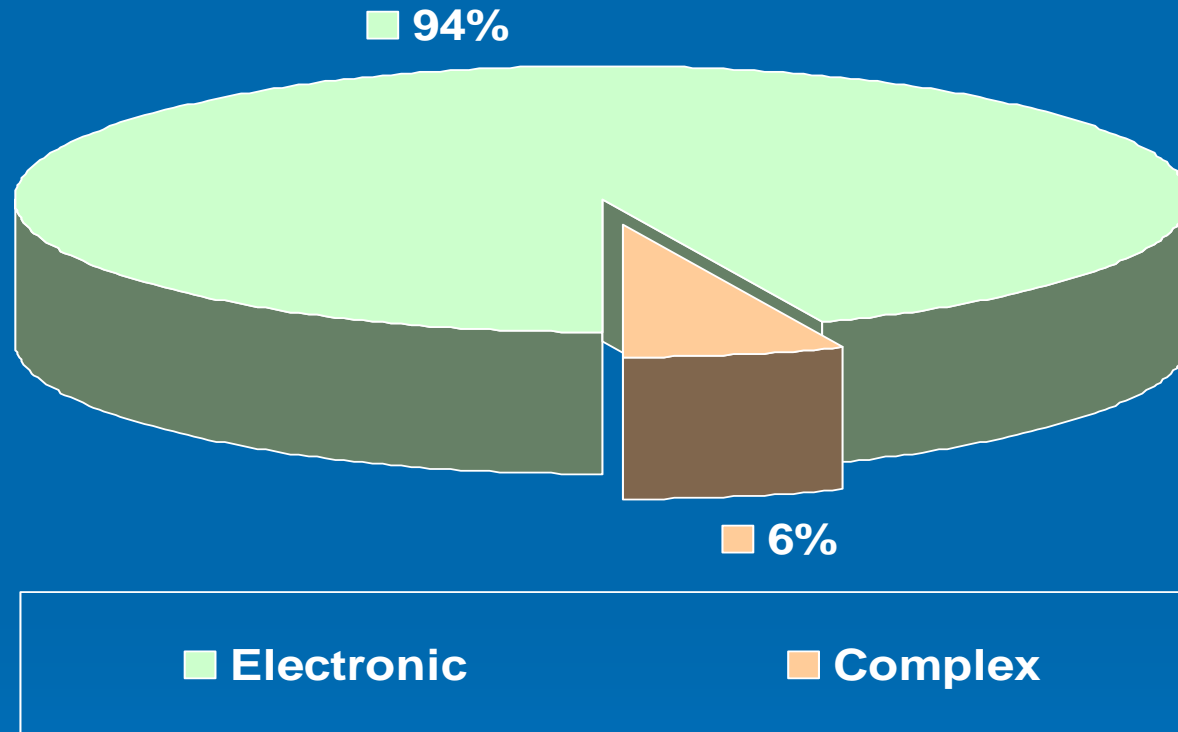


Electronic Submission

Electronic Submission Update

- Individual Fellowship Awards transitioned to electronic submission on August 8, 2009.
- Mechanisms that transitioned January 25, 2010 (NOT-OD-10-008) include:
 - Institutional National Research Service Awards (T32, T34, T35, T36, T90)
 - Other Institutional Training Grants (D43, D71, T01, T02, T03, T14, T15, T37, TU2, U2R)
 - Institutional Career Development Programs (K12)
- Guide Notice NOT-OD-10-016 (released November 23, 2009) announced the availability of new application instructions and forms for paper-based PHS 398 applications and electronic SF 424 (R&R) applications.

Transition to Electronic Submission



- NIH has successfully transitioned all grant programs to electronic submission, with the exception of **Complex, Multi-project Applications**.
- More at: http://era.nih.gov/ElectronicReceipt/strategy_timeline.htm

Compatible Software

➤ Adobe Reader:

- Only specific Adobe Reader versions are compatible with Grants.gov forms

➤ PDF conversion program:

- Attachments **must** be converted to PDF

➤ Grants.gov Download Software page:

- http://www.grants.gov/help/download_software.jsp

Tips for eRA Commons Success

- Start early—allow at least 4 weeks to complete registration.
 - NIH 2-week “good faith effort” for Commons registration.
- Grants.gov and Commons registrations may be completed simultaneously once DUNS# is obtained.
- Update CCR information yearly to keep Grants.gov credentials active.
- Do not combine Signing Official and PI roles on a single Commons Account.
- If PD/PI has a Commons account, affiliate them to your organization rather than creating new account.
- PIs should update their Commons profile prior to submitting an application (e.g. degree info is used to determine Early Stage Investigator eligibility).
- More at: http://era.nih.gov/ElectronicReceipt/avoiding_errors.htm

Available Resources

- Resources for the Adobe transition can be found on:
 - NIH Electronic Submission of Grant Applications Web site:
<http://era.nih.gov/ElectronicReceipt/>
 - Grants.gov Web site (Applicant Resources):
<http://grants.gov/applicants/resources.jsp>

X-Train



X-Train Open to All Institutions

- X-Train is a new system to improve the administration of NIH Training Grants.
 - Allows PIs and staff to electronically submit appointment forms and termination notices.
 - Allows institutional staff to track status and timing of appointment actions.
 - Available for all NIH NRSA Research Training Grants (i.e., T32, T34, T35, T90, TL1 and TU2), as well as R25 and R90 activity codes.
- Accommodates separate appointments for ARRA supplements to training grants.
- Accessible through eRA Commons.
- NIH continues to develop X-Train for use in other training programs in the future.
- Moving towards mandating use in January 2011.
- More at: <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-09-121.html>



Closeout

Closeout: Final Reports

- Grantees are **strongly encouraged** to submit closeout documents electronically through the eRA Commons!
- Documents are due within 90 days of project period end date.
 - Final Financial Status Report (**now required electronically**)
 - Final Inventions Statement & Certification
 - Final Progress Report
- Grantees must ensure that there are no discrepancies between the final Financial Status Report (SF-269 or 269A) and the Payment Management System's Federal Cash Transaction Report (SF-272).
- More at: <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-08-061.html>

NIH Centralized Processing Center

- NIH encourages electronic submission of closeout documents through the eRA Commons.
- Centralized office accepts receipt of all non-financial, paper-based closeout documents
 - Final Progress Report
 - Final Invention Statement and Certification
- Mail to the Central NIH unit at:

NIH Centralized Processing Center
6705 Rockledge Drive, Room 2207, MSC 7987
Bethesda, MD 20892-7987 (for regular or US Postal
Service Express mail)

Bethesda, MD 20817 (for other courier/express mail
delivery only)

Helpful NIH Technical Assistance Resources



New Tools to Search NIH Funding: RePORT

- The Reports, Data and Analyses website (RePORT) was released in 2008 and expanded in 2009 with addition of RCDC data (Research, Condition and Disease Categorization process).
- Replaces the former Award Information and Data web page and provides:
 - Quick access to “Frequently Requested Reports”, FAQs;
 - Efficient search tools for locating data and reports
 - Links to funding estimates for certain research areas, conditions, and diseases.
 - Includes ARRA-specific data queries
- More at: <http://report.nih.gov>

New Tools to Search NIH Funding: RePORTER

- Research Portfolio Online Reporting Tool Expenditures and Result (RePORTER)
 - Replaces CRISP, which was retired on 9/1/2009.
 - Combines NIH project databases and funding records, PubMed abstracts, full-text articles from PubMed Central, and information from the U.S. Patent and Trademark Office with a robust search engine, allowing users to locate descriptions and funding details on NIH-funded projects along with research results.
- More at: <http://projectreporter.nih.gov/reporter.cfm>

A photograph of a large, ornate fountain in Central Park, New York City. The fountain has multiple tiers and water spraying upwards. In the background, the New York State Capitol building is visible, surrounded by lush green trees. The scene is bright and sunny.

Frequently Asked Questions

Q: Does NCI Receive Late or Incomplete Applications and Closeout Reports?

A: Definitely, Yes.

- A recent Inspector General report showed 40% of applications coming in late, in addition to late closeout reports.
- It is necessary for grantees to submit applications and closeout reports on time.
- Once applications are received and reviewed, additional delays are caused when applications are incomplete. Considerable IC resources are diverted requesting late applications and missing items on incomplete applications.



Q: Does NIH Still Accept Unsolicited Grant Applications?

A: Yes

Parent Announcements (available on Grants.gov and NIH web pages) are used for “unsolicited” or “Investigator-initiated” applications.

Other funding opportunity announcements include:

- Program Announcements
 - Statement of new or ongoing NIH interest in a certain research area.
- Requests for Applications (RFAs)
 - Statement soliciting applications in a well-defined scientific area to accomplish specific program objectives.
- All available at: <http://grants.nih.gov/grants/guide/index.html>

Q: Does NIH have a Cap on Consultant Fees?

A: No

There is no cap on consultant fees and the NIH salary cap does not apply.

However...

- Grantees must have written policies for paying consultants that:
 - Are consistently applied regardless of fund source.
 - Include conditions for paying consultant fees.
- Consultants must be properly classified.
 - Consultants are defined as individuals who provide professional services or advice for a fee, but normally are not employees of the organization. This also includes firms that provide advice or services.

Q: Are Consortium F&A Costs Included as Part of an Applicant's Direct Cost Limit?

A: No

Applicants are to exclude the facilities and administrative (F&A) costs requested by consortium participants when determining if the budget exceeds a direct cost limit.

- This policy applies to:
 - \$250K direct cost calculation for modular budgets
 - \$500K direct cost calculation for NIH data sharing policy and requirement to contact IC staff for unsolicited applications requesting over \$500K
- This policy does not apply to:
 - Small Business Innovation Research (SBIR) grants
 - Small Business Technology Transfer (STTR) grants
- More at: <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-05-004.html>

Q: As a PI, What Happens if I Change Institutions Mid-grant?

A: Prior, written approval is required for transferring legal and administrative authority for a grant to a different organization.

- Transfer approval is **not automatic** and requires approval from both NIH and the original grantee organization.
- Contact your GMO **before moving** to initiate the transfer process.
 - 60 days notice is requested prior to transferring to the new institution.
- Grants to individuals may not be transferred but individual fellowships may transfer to a new sponsoring institution.

Q: How Do I Change a Single PD/PI Application to Multiple PD/PI?

A: This can only be done through a competing application (e.g. renewal, resubmission, or competing revision). This change **cannot** be made on a non-competing active grant or through an administrative supplement request.

- For renewals & resubmissions: The PD/PI of the previous grant should be listed as the Contact PD/PI on the Multiple PD/PI grant.
 - If another PD/PI is listed as a Contact PD/PI, the application must also show as a Change of PD/PI.
- For competing revisions: The Contact PD/PI must be the individual previously noted as the PD/PI.
- The renewal, resubmission, or revision application must now include the Multiple PD/PI leadership plan.
- Multiple PI FAQs available at http://grants.nih.gov/grants/multi_pi/faq.htm

Q: Are Fellowship Candidates Required to Register in the eRA Commons?

A: Yes

Applicant organizations should register any individual fellows submitting applications to NIH and AHRQ.

- PI Role in the Commons does not provide special status – only a record in the system that provides administrative authority to see pertinent application documents (e.g. summary statements, scores, submission status, etc.).
- Individual Fellows registered by any organization other than the sponsoring organization should not have more than one eRA Commons account.
- More at: <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-07-003.html>

Q: Are Individuals in a Postdoctoral Role Required to Register in the eRA Commons?

A: Yes

All individuals with a postdoctoral role who participate in a project for at least one person month or more are required to register and obtain a Commons ID.

- NIH is required under the NIH Reform Act of 2006 (Public Law 109-482) to collect identifying and demographic information and report on those in a postdoctoral role on research grants.
- The eRA Commons ID must be reported for all postdocs listed on the All Personnel Report in the PHS 2590.
- The Commons Postdoctoral role should NOT be used for individuals submitting Individual Fellowships.

Q: Do ARRA Reporting Requirements Apply to All ARRA-Funded Grant and Cooperative Agreement Recipients?

A: Yes

All ARRA-funded, NIH extramural grant or cooperative agreement recipients must report information in accordance with Section 1512 of the Recovery Act on a quarterly basis using the www.FederalReporting.gov website.

- Prime recipients are responsible for fulfilling the reporting requirements for both prime and sub-recipients; however, prime recipients may delegate the reporting responsibilities to sub-recipients.
- The prime recipient is the grantee institution.
- For details, see http://grants.nih.gov/recovery/faqs_recovery.html#Vla1

Q: Do ARRA Reporting Requirements Apply to All ARRA-Funded Supplements Even When the Parent Grant is Non-ARRA?

A: Yes

All ARRA-funded recipients must submit reports within 10 days of the end of each federal quarter.

- Reports must be submitted to www.FederalReporting.gov and possibly to the awarding agency.
- Separate Financial Reporting
 - Separate SF 272 and Financial Status Reports will be required to be submitted covering this additional funding.
 - These are in addition to required financial reports for the parent grant.
- Separate Closeout Documents
 - Separate Final Progress Reports, Final Financial Status Reports, and Final Invention Statements will also be required to close out the Recovery Act funding at the time ARRA funding ends.
 - These closeout reports for the ARRA funding are required even when the parent grant continues.

Cancer Survivors

- Death rates for the four most common cancers (prostate, breast, lung, and colorectal), as well as for all cancers combined, continue to decline.
- The rate of cancer incidence has declined since the early 1990s.

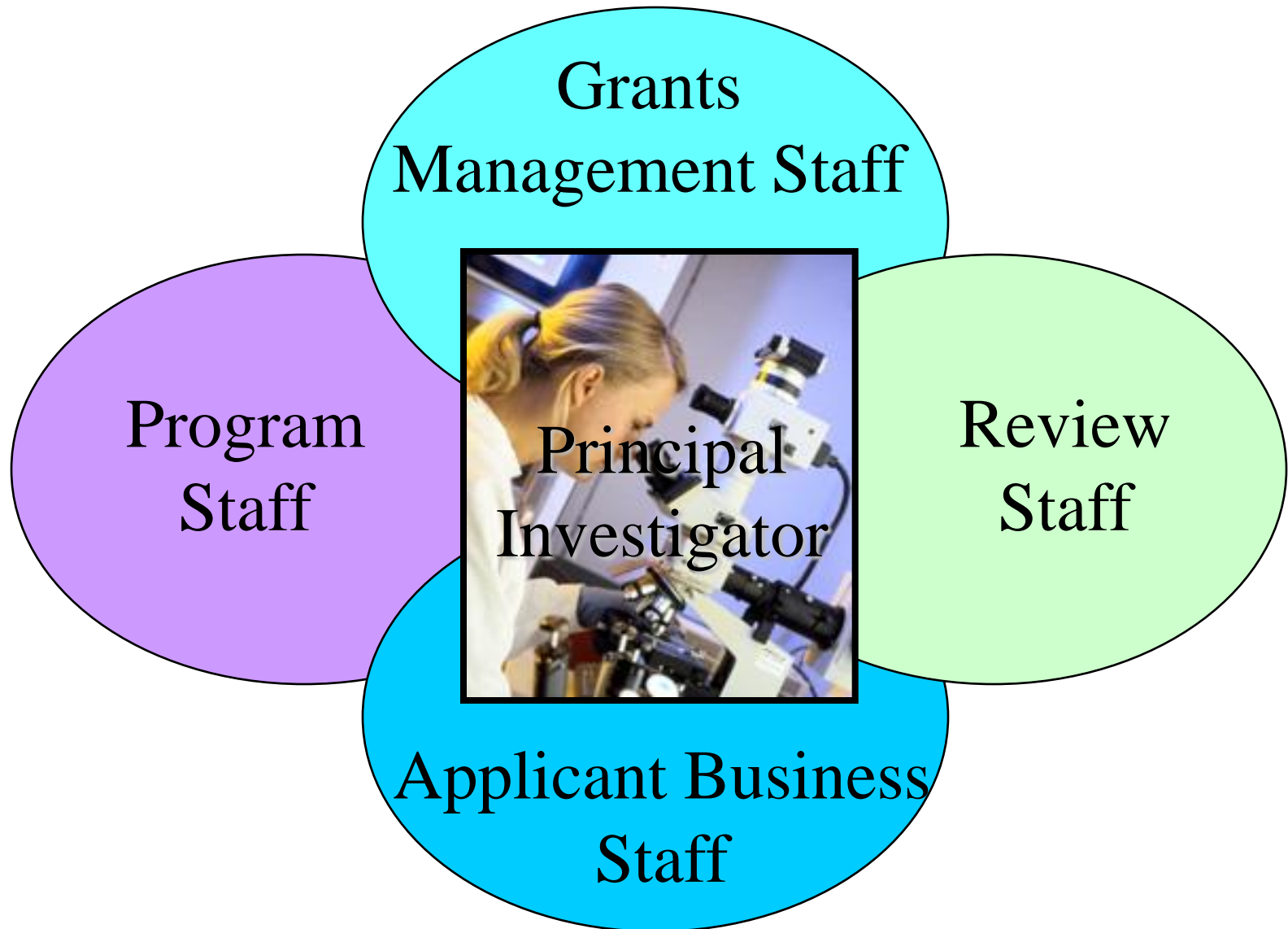
There are
approximately
12 million cancer
survivors in the
United States!



Regardless of what part we play in the Grants Process (large or small), our collective contributions and efforts are making a difference in winning the battle against cancer.



Collaborating to Eradicate Cancer



Working together...

Clinicians

Scientists

Researchers

**Research
Administrators**

Volunteers

Patients

American Public

We will continue to make a difference.

GOT QUESTIONS?...
I MAY HAVE ANSWERS





Useful Resources

Grants Information: Who to Contact

- **Institutional Resources** – Utilize the expertise of your organization's Office of Sponsored Programs

Application Specific Questions

- **Administrative** – Contact the Grants Management Specialist at the awarding Institute/Center
- **Scientific/Programmatic** – Contact the designated Program Official/Director at the awarding Institute/Center
- **Review** – Contact the assigned Scientific Review Officer



Grants Information: Who to Contact

- Grants Administration individuals at all NIH ICs
 - http://grants.nih.gov/grants/staff_list_grants_admin.htm
- NIH Chief Grants Management Officers
 - http://grants.nih.gov/grants/stafflist_gmos.htm
- Grants Policy Interpretation & Consultation
 - E-mail: GrantsPolicy@od.nih.gov
 - Phone: 301-435-0949
- Grants Compliance Issues
 - E-mail: GrantsCompliance@nih.gov
 - Phone: 301-435-0949

Grants Information: Who to Contact

- General Application Questions (including eSubmission guidelines, resources & referrals, application review & award process, etc.)
 - E-mail: GrantsInfo@nih.gov
 - Phone: 301-435-0714
- Customer Support for Grants.gov (navigating forms, aspects of submitting through the system, resources available, etc.)
 - E-mail: support@grants.gov
 - Website: <http://grants.gov>
 - Phone: 1-800-518-4726
- eRA Commons Help Desk (Including commons registration help, application verification, Commons functionality questions, etc.)
 - E-mail: commons@od.nih.gov
 - Webpage: <https://commons.era.nih.gov/commons/index.jsp>
 - Phone: 301-402-7469 (Toll free: 866-504-9552)

Helpful Websites

- NIH searchable database of RFAs, PAs, and Guide Notices
 - <http://grants1.nih.gov/grants/guide/index.html>
- NIH Grants Policy Statement (Rev. 12/03)
 - http://grants1.nih.gov/grants/policy/nihgps_2003/index.htm
- NIH Extramural Nexus – monthly newsletter for the extramural community
 - <http://grants.nih.gov/grants/nexus.htm>
- Electronic Submission of Grant Applications Homepage
 - <http://era.nih.gov/ElectronicReceipt/index.htm>
- CRISP database – search to analyze an Institute's portfolio of funded projects, research areas, and more
 - http://crisp.cit.nih.gov/crisp/crisp_query.generate_screen
- Grant Application Basics
 - http://grants.nih.gov/grants/grant_basics.htm

NIH OER Listserv

Addresses and Instructions

- Office of Biotechnology Activities (OBA)
 - https://list.nih.gov/archives/oba_news.html
- Office of Human Research Protections (OHRP)
 - <http://www.hhs.gov/ohrp/news/distributionlist.html>
- Office of Laboratory Animal Welfare (OLAW)
 - <http://grants2.nih.gov/grants/olaw/references/list.htm>
- eSubmission
 - <http://era.nih.gov/ElectronicReceipt/listserv.htm>
 - Separate listservs available for scientists and administrators
- NIH Guide for Grants and Contracts
 - <http://grants.nih.gov/grants/guide/listserv.htm>
 - The official publication for NIH medical and behavioral research Grant Policies, Guideline and Funding Opportunities